

118TH CONGRESS  
1ST SESSION

# H. R. 4529

To amend the Public Health Service Act regarding guidance documents of the Centers for Disease Control and Prevention, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JULY 11, 2023

Mrs. RODGERS of Washington introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Public Health Service Act regarding guidance documents of the Centers for Disease Control and Prevention, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Public Health Guid-  
5 ance Transparency and Accountability Act of 2023”.

6 **SEC. 2. CDC GUIDANCE DOCUMENTS.**

7 The Public Health Service Act (42 U.S.C. 201 et  
8 seq.) is amended by inserting after section 317V of such  
9 Act (42 U.S.C. 247b–24) the following:

1 **“SEC. 317W. CDC GUIDANCE DOCUMENTS.**

2 “(a) GOOD GUIDANCE PRACTICES.—

3 “(1) IN GENERAL.—The Secretary acting  
4 through the Director of the Centers for Disease  
5 Control and Prevention (in this section referred to  
6 as the ‘Secretary’) shall, by regulation, develop, es-  
7 tablish, and maintain good guidance practices set-  
8 ting forth the policies and procedures of the Centers  
9 for the development, issuance, dissemination, and  
10 use of guidance documents.

11 “(2) CONTENTS.—The regulation required by  
12 paragraph (1) shall—

13 “(A) incorporate each requirement of sub-  
14 sections (b) through (k); and

15 “(B) require guidance documents to be de-  
16 veloped with public participation.

17 “(3) INITIAL REGULATION.—The Secretary  
18 shall—

19 “(A) not later than 30 days after the date  
20 of enactment of the Public Health Guidance  
21 Transparency and Accountability Act of 2023,  
22 initiate the rulemaking process for the initial  
23 regulation under paragraph (1); and

24 “(B) not later than 2 years after the date  
25 of enactment of the Public Health Guidance

1           Transparency and Accountability Act of 2023,  
2           finalize such regulation.

3           “(b) NO CREATION, CONFERRING, RESTRICTING, OR  
4 REVOKING OF RIGHTS, RESPONSIBILITIES, OR LIABIL-  
5 ITIES.—Guidance documents of the Centers for Disease  
6 Control and Prevention may present views on matters  
7 under the jurisdiction of the Centers, but shall not—

8           “(1) create, confer, restrict, or revoke any  
9           rights, responsibilities, or liabilities for or on any  
10          person;

11          “(2) be treated (including in any civil or crimi-  
12          nal proceeding) as having the force and effect of law;  
13          or

14          “(3) include any provision that—

15                  “(A) is binding on the public or a State,  
16                  local, Tribal, or Territorial government; or

17                  “(B) requires an individual to take or re-  
18                  frain from an action.

19          “(c) EFFECT ON CDC EMPLOYEES AND CONTRAC-  
20 TORS.—Although guidance documents of the Centers for  
21 Disease Control and Prevention shall not be binding on  
22 the Secretary or the Director of the Centers, the Secretary  
23 shall ensure that employees and contractors of the Centers  
24 do not deviate from such guidance documents without ap-  
25 propriate justification and supervisory concurrence.

1 “(d) TRAINING.—The Secretary shall—

2 “(1) provide training to employees of the Cen-  
3 ters for Disease Control and Prevention in how to  
4 develop, issue, disseminate, and use guidance docu-  
5 ments in accordance with the regulation under sub-  
6 section (a)(1); and

7 “(2) monitor the development, issuance, dis-  
8 semination, and use of such documents to ensure  
9 compliance with the regulation under subsection  
10 (a)(1).

11 “(e) PUBLIC PARTICIPATION IN PROCESS.—

12 “(1) IN GENERAL.—Subject to paragraph (2),  
13 the Secretary shall ensure that public participation  
14 required by subsection (a)(2)(B) occurs prior to fi-  
15 nalization and implementation of any guidance docu-  
16 ment, including any guidance document that sets  
17 forth—

18 “(A) initial interpretations of a statute, a  
19 regulation, or an emerging public health situa-  
20 tion;

21 “(B) changes or updates in interpretation  
22 or policy that are of more than a minor nature;

23 “(C) complex scientific issues; or

24 “(D) highly controversial issues.

1           “(2) EXCEPTIONS.—The Secretary may provide  
2           for public participation required by subsection  
3           (a)(2)(B) to occur after the guidance document has  
4           been finalized and after implementation of the guid-  
5           ance document has begun if—

6                   “(A) the Secretary determines that com-  
7                   mencing public participation sooner is not fea-  
8                   sible or appropriate; or

9                   “(B) the guidance document sets forth  
10                  only existing practices or minor changes in pol-  
11                  icy.

12           “(3) CONSIDERATION.—In finalizing, imple-  
13           menting, and revising a guidance document, the Sec-  
14           retary shall take into account public comments re-  
15           ceived during public participation on the guidance  
16           document.

17           “(f) UNIFORM NOMENCLATURE.— In developing  
18           guidance documents of the Centers for Disease Control  
19           and Prevention, the Secretary shall ensure uniform no-  
20           menclature for such documents and uniform internal pro-  
21           cedures for approval of such documents.

22           “(g) INDICATION OF NONBINDING NATURE.—The  
23           Secretary shall ensure that guidance documents of the  
24           Centers for Disease Control and Prevention and revisions

1 of such documents are properly dated and indicate the  
2 nonbinding nature of the documents.

3 “(h) PERIODIC REVIEW.—The Secretary shall peri-  
4 odically review all guidance documents of the Centers for  
5 Disease Control and Prevention and, where appropriate,  
6 revise such documents.

7 “(i) LIST OF DOCUMENTS.—The Secretary shall  
8 maintain electronically and update and publish periodi-  
9 cally in the Federal Register a list of all guidance docu-  
10 ments of the Centers for Disease Control and Prevention.

11 “(j) PUBLIC AVAILABILITY.—The Secretary shall  
12 make available to the public the list under subsection (i)  
13 and all guidance documents of the Centers for Disease  
14 Control and Prevention, including by posting on the public  
15 website of the Centers.

16 “(k) APPEALS MECHANISM.—The Secretary shall en-  
17 sure that an effective appeals mechanism is in place to  
18 address complaints that guidance documents of the Cen-  
19 ters for Disease Control and Prevention are not being de-  
20 veloped, issued, disseminated, or used in accordance with  
21 this section.”.

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